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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/08, A61M 16/00, A62B 7/00, F16K 31/02 | A1

(11) International Publication Number: WO 98/33433

(43) International Publication Date: 6 August 1998 (06.08.98)

(21) International Application Number: PCT/US98/01987

(22) International Filing Date: 30 January 1998 (30.01.98)

(30) Priority Data:
60/036,407 31 January 1997 (31.01.97) US

(71) Applicant: HEALTHDYNE TECHNOLOGIES, INC. [US/US]; 1255 Kennestone Circle, Marietta, GA 30066 (US).

(72) Inventors: SERVIDIO, John, L.; 1092 Cheney Place, Marietta, GA 30064 (US). GRIFFIN, Don; 3587 Mill Creek Trail, Smyrna, GA 30082 (US). HURST, Gregg; 1271 Woolf Valley Court, Acworth, GA 30132 (US). ANDERSEN, Robert; Apartment 711, 1001 Burnt Hickory Road, Marietta, GA 30064 (US). MOORE, Erik; 3757 Upland Drive, Marietta, GA 30066 (US). KATRAGADDA, Venkata; Apartment B, 3390 Chelsea Park Lane, Norcross, GA 30092 (US). PANTELIAS, Niki, R.; 1366 Fenway Circle, Decatur, GA 30030 (US).

(74) Agents: BOSS, Gerald et al.; Troutman Sanders LLP, Suite 5200, 600 Peachtree Street, N.E., Atlanta, GA 30308-2216 (US).

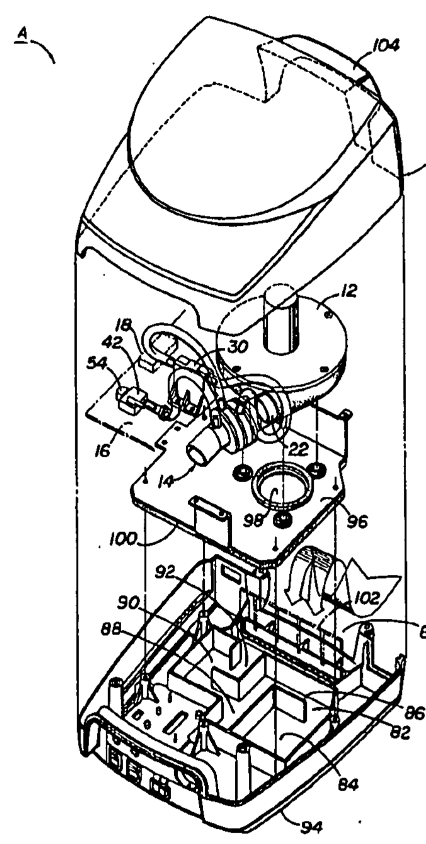
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: METHOD AND APPARATUS FOR TREATING AIRWAY DISORDERS

(57) Abstract

This invention is a device (A) for the treatment of sleep apnea including a variable speed blower (12) which is computer (18) controlled, a flow meter (14) which feeds flow and pressure data to the computer to control the blower.



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METHOD AND APPARATUS FOR TREATING AIRWAY DISORDERS

BACKGROUND OF THE INVENTION

This application claims priority based on United States Provisional Application No. 60/036,407 filed on January 31, 1997. This invention relates generally to a device for treating airway disorders and more particularly to an apparatus for treating obstructive sleep apnea which utilizes a variable speed blower in combination with control features utilizing correction factors for elements located within the apparatus for maintaining an accurate operation of the apparatus for treating obstructive sleep apnea.

The treatment of airway disorders such as obstructive sleep apnea involves subjecting a patient to a positive pressure flow of air. Such methods include providing continuous positive airway pressure (CPAP) and bi-level positive airway pressure treatment which incorporate a presentation of positive air pressure to the airways of a patient. Bi-level treatment involves presenting a high pressure to the patient during inhalation and a lower pressure during exhalation. The manufacturing of such devices for treating sleep apnea include incorporating pressure control devices and flow metering devices into the devices. The accuracy of the pressure and flow metering devices is critical to ensure the correct operation of the sleep apnea treatment system. Due to the inconsistencies of the operational mechanics of these devices resulting from the manufacturing of the devices, a need exists for ensuring that the sleep apnea treatment system operate correctly as prescribed in providing accurate pressure treatment.

Furthermore, since the treatment of obstructive sleep apnea requires that the treatment systems be utilized as prescribed by a patient, a need exists for monitoring the utilization of the treatment systems to ensure that the patient is complying with treatment.

Also, such machines tend to be noisy making sleep difficult and thus creating a need for a quiet system.

Previously, CPAP and bi-level positive airway pressure devices have been created. However, such devices tend to be expensive. Accordingly, a need arises for a low cost device making it economical for people suffering from obstructive sleep apnea to have access to a home health care unit for treatment of the sleep apnea disorder in a reliable manner.

Accordingly, it is an object of the present invention to provide a low cost sleep apnea treatment device;

Additionally, it is an object of the present invention to provide correction factors for ensuring the reliable operation of sleep apnea treatment devices;

Furthermore, it is an object of the present invention to provide for correction factors for a flow and pressure measuring element utilized in the system;

Also, it is an object of the present invention to monitor patient compliance with the sleep apnea treatment as prescribed by a doctor;

Further, it is an object of the present invention to provide for a quiet sleep apnea treatment device;

Additionally, it is an object of the present invention to provide a sleep apnea treatment device having a control transition from both the inhalation/exhalation transition.

SUMMARY OF THE INVENTION

The above objectives are accomplished according to the present invention by providing a device for the treatment of sleep apnea. The device includes a variable-speed blower for providing an airflow under pressure to a patient for treating sleep apnea. A motor controller is interconnected with the variable speed blower for manipulating the

speed of the blower for providing air at a predetermined pressure. A flow meter assembly is inline between the variable speed blower and a patient for receiving the airflow. The flow meter assembly includes a flow port for communicating a portion of the airflow to a flow sensor for monitoring the flow of the airflow. The flow meter assembly also includes a pressure port in communication with a pressure sensor for monitoring the pressure of the airflow. An input device enables the inputting of the desired pressure of the airflow. A microprocessor receives the inputted desired pressure and the flow measured by the flow sensor and the pressure measured by the pressure sensor. The microprocessor controls the operation of the motor controller for manipulating the airflow provided by the variable speed blower depending on the values of the inputted desired pressure, the measured flow and the measured pressure.

DESCRIPTION OF THE DRAWINGS

The construction designed to carry out the invention will hereinafter be described, together with other features thereof.

The invention will be more readily understood from a reading of the following specification and by reference to the accompanying drawings forming a part thereof, wherein an example of the invention is shown and wherein:

FIG. 1 is an exploded view of a sleep apnea treatment device according to the present invention;

FIG. 2 is a perspective view of a flow meter assembly according to the present invention;

FIG. 3 is an exploded view of a flow meter assembly according to the present invention;

FIG. 4 is an operational schematic of a flow meter assembly according to the present invention;

FIG. 5 is an operational schematic of a patient monitoring system utilized in a sleep apnea treatment device according to the present invention;

FIG. 6 is an operational schematic of a sleep apnea treatment device according to the present invention;

FIG. 7 is an operational schematic of a sleep apnea treatment device according to the present invention;

FIG. 8 is a diagram illustrating application of rise time according to the present invention;

FIG. 9 is a diagram illustrating application of fall time according to the present invention.

DESCRIPTION OF THE PREFFERED EMBODIMENT

As shown in FIG. 1, sleep apnea treatment device A includes a general housing assembly 10 which houses variable speed blower 12 and flow meter assembly 14. Printed circuit board 16 carries microprocessor 18, which among other features described hereinafter, manipulates the operation of variable speed blower 12 depending on the flow and pressure values measured by flow meter assembly 14 . The speed of variable speed blower 12 produces pressurized air which is communicated to a patient through a conduit interconnected with flow meter assembly 14 for treating sleep apnea.

In the preferred embodiment, sleep apnea treatment device A may provide different pressure levels of pressurized air to a patient depending on whether the patient is inhaling or exhaling. Such variation in pressure levels is known as bi-level treatment wherein a

higher level of positive airway pressure is supplied during inhalation and a lower level of positive airway pressure is supplied during exhalation. The transition from presenting the higher and lower pressures utilizes an inhalation/exhalation module as described in U.S. Patent application having serial no. 08/794,659, incorporated by reference which utilizes the flow value determined by flow meter assembly 14.

Flow meter assembly 14 is shown in FIGs. 2, 3 and 4. Flow meter assembly 14 includes blower connection member 20 for mounting flow meter assembly 14 in fluid communication with outlet 22 of variable speed blower 12 for receiving pressurized air. First flow meter center member 24 receives pressurized air from blower connection member 20. First screen 26 is disposed between blower connection member 20 and first flow meter center member 24 for removing airflow disruptions and creating a smooth airflow. First flow meter center member 24 carries flow sensor port 28 for directing airflow to flow sensor 30. Second flow meter center member 32 is interconnected with first flow meter center member 24 for receiving pressurized air. Second flow meter center member 32 includes flow sensor receiver port 34 for receiving the flow of air which had previously been directed from flow sensor port 28 to flow sensor 30. Second screen 36 is disposed between first and second flow meter center members 24 and 32 for creating a pressure drop between the two center members thereby influencing airflow to pass through flow sensor port 28 to flow sensor 30. The majority of airflow passes directly from first flow meter center member 24 to second flow meter center member 32 through second screen 36. Flow meter assembly 14 further includes flow meter outlet member 38 for directing the pressurized airflow to a conduit for presentation to a patient. Flow meter outlet member 38 includes pressure port 40 which is interconnected with pressure sensor 42 which is preferably a transducer for determining the pressure of airflow through the sleep

apnea treatment system. By measuring the pressure of airflow in the system at the point where airflow enters the conduit which is interconnected to a patient, an accurate reading of the air pressure presented to a patient may be determined. Third screen 44 is disposed between second flow meter center member 32 and flow meter outlet member 38 for removing airflow disruptions and creating a smooth airflow when airflow is negative flowing from a patient back through flow meter assembly 14.

The respective members of flow meter assembly 14 each include interior portions for receiving the respective screens. The overall assembly is assembled using ultrasonic welding techniques.

Flow sensor 30 monitors the air flow through sleep apnea treatment system A. To contain costs, flow sensor 30 is preferably a flow transducer of a mass airflow type producing an analog voltage signal. Accordingly, flow transducer 30 operates on a flow versus voltage relationship. However, due to the inherent operational characteristics of mass airflow transducers, a particular change in flow value does not always produce the same change in voltage results. Thus, the relationship between voltage and flow in the analog flow transducer is non-linear. Thus a flow correction factor is computed for the particular flow transducer 30 utilized which linearizes the non-linear relationship between flow and voltage.

To compute the flow correction factor for flow transducer 30, during the manufacturing process of sleep apnea treatment device A, flow tests are conducted on flow transducer 30. The tests entail simultaneously presenting an airflow through a control flow transducer and flow transducer 30. While the airflow is presented, the corresponding voltage is measured by flow transducer 30 at one millisecond intervals for sixty-four milliseconds producing sixty-four sampled values which are averaged to produce an average

voltage value for flow transducer 30 at that particular airflow value. Also, the flow value indicated by the control flow transducer at the same specific airflow is recorded. Thus, a control flow versus mass airflow flow transducer recorded voltage relationship table is produced. Overall, in the preferred embodiment, sixteen pairs of flow points are calculated at sixteen different airflow levels, preferably those airflow levels which produce flow readings are between negative one hundred and thirty-five liters per minute and two hundred and two liters per minute. These values reflect extreme operating conditions defining operational boundaries and would not be present during actual operation by a patient. Overall, sixteen pairs of flow values are tabulated creating a relationship table between the control flow transducer and also a corresponding voltage value produced by flow transducer 30;

i.e.

Control Flow Airflow Value$_1$	**Flow Transducer Voltage Value$_1$**
Control Flow Airflow Value$_2$	**Flow Transducer Voltage Value$_2$**
"	"
"	"
Control Flow Airflow Value$_{16}$	**Flow Transducer Voltage Value$_{16}$**

Since the relationship between the voltage measured by flow transducer 30 with respect to airflow is non-linear, the discrepancies between control flow airflow values one to sixteen with respect to flow transducer voltage values one to sixteen will also be non-linear. Accordingly, to establish a flow correction factor for flow transducer 30, a fourth order polynomial is created utilizing a Chebyshev polynomial regression technique on the established flow relationship table. The Chebyshev regression is used to produce the equation Flow $= C_0 + C_1 * \text{Voltage} + C_2 * \text{Voltage}^2 + C_3 * \text{Voltage}^3 + C_4 * \text{Voltage}^4$. By utilizing the Chebyshev regression on the established flow table, coefficients C_0, C_1, C_2,

C_3, and C_4 are calculated for that specific flow transducer. These coefficient values are stored on EEPROM 46 as a flow calibration model 48 and accessed during operation of flow transducer 30 for producing a flow value indicative of the flow through sleep apnea treatment device A. The flow value is utilized during inspiration/exhalation detection as explained in U.S. patent application number having serial number 08/794659, incorporated by reference, and in controlling the operation of blower 12.

Another factor utilized in the operation of sleep apnea treatment device is the pressure value which is measured by pressure sensor 42. Pressure sensor 42 is preferably a pressure transducer which measures voltage and produces a corresponding pressure value for that particular voltage value. The relationship between voltage and pressure is linear and may be represented by $P = m(\text{voltage}) + b$, where m, the span variable, and b, the offset variable, are linear coefficients. However, both coefficients m and b vary with temperature. Thus, the temperature of pressure transducer 42 influences the pressure value. Typically, the span coefficient with respect to temperature is known, but the offset coefficient b is unknown. Accordingly, during the manufacturing process of sleep apnea treatment device A, pressure transducer 42 is tested at different temperatures with respect to a control pressure transducer to determine the offset coefficient b at different temperatures for that particular pressure transducer.. The relationship between offset coefficient b and temperature can be approximated as linear enabling a linear profile of b versus temperature over a range of temperatures to be created. In the preferred embodiment, the offset coefficient b is calculated at three temperatures: b at 25°C; b at 40°C; and b at 55°C and a linear pressure/temperature profile is created for temperatures in between. This pressure/temperature profile 52 is stored in EEPROM 46 for the respective sleep apnea treatment device. For large correction factors, a large correction

factor is stored EEPROM 46 and then set in a digital potentiometer as b_{pot} such that offset coefficient b consists of $b_{pot} + b$ at the respective temperature.

To ensure the accuracy of the pressure value produced by pressure transducer 42 during operation of sleep apnea treatment device A, temperature sensor 54 is located adjacent pressure transducer 42 on printed circuit board 16. Accordingly, microprocessor 18 utilizes the temperature reading from temperature sensor 54 in combination with the pressure reading from pressure transducer 42 and pressure/temperature profile 52 for establishing a temperature corrected pressure value. This temperature corrected pressure value is utilized for controlling blower 12 in delivering the required treatment air pressures to a patient.

Also, due to the mechanics of pressure transducer 42, over time of operation pressure transducer 42 may require further calibration. This is accomplished by auto zeroing the pressure transducer at start up of sleep apnea treatment device A. At the start up, air flow is zero, thus the pressure reading should be zero. If the pressure reading at start up is not zero, an auto-zero correction factor 56 is calculated to adjust the pressure value to zero. This auto-zero correction factor 56 is utilized by microprocessor 18 in calculating the system pressure value during the operation of sleep apnea treatment device A during the treatment cycle. The auto-zero factor is calculated each time sleep apnea treatment device A is initially powered up.

As shown in FIG. 5, patient monitoring system 58 monitors the utilization of sleep apnea treatment device A by a patient. As shown in FIGs. 6 and 7, microprocessor 18 utilizes real time clock 60 for noting the time of certain events. The first time event noted is when sleep apnea treatment device A is initially powered up. This time is recorded in a log in EEPROM 46. Patient monitoring system 58 also monitors if a patient is breathing

on the system. If breaths in a range between four to forty breaths per minute are detected, it is assumed that a patient is utilizing the system. At this event, the time is noted and a compliance low meter is started. If in the future it is noted that a breathing rate less than four breaths per minute or greater than forty breaths per minute is noted, it is assumed that a patient is not utilizing the system and the compliance meter is stopped at this time and the time of occurrence is noted. Also, the current time while the machine is operating is repeatedly stored in memory and when the machine is turned off, the last time is noted as the log off time. The total time that the machine is used by the patient is stored in a compliance meter.

As shown in FIG 6, sleep apnea treatment device A also includes an optical transmitter 70 and a optical receiver 72. These devices utilize light waves to enable sleep apnea treatment device A to be manipulated by remote control and also allows a recording receiving device to monitor the operations of sleep apnea treatment device A for analyzing the treatment of the patient utilizing sleep apnea device A. For instance, the various flows and pressures occurring with respect to time during the operation of sleep apnea treatment device A may be monitored by the remote recording device for further analysis of the sleep apnea treatment for that particular patient.

To provide a patient with comfort, a rise time feature 74 may be selected by the patient. As shown in FIG. 8, rise time feature 74 defines a profile in the rise of pressure from the lower exhalation pressure to the higher inhalation pressure when the sleep apnea treatment device A switches from exhalation to inhalation pressure for the treatment of sleep apnea. Rise time includes two separate parameters. The first parameter is the time during which the exhalation pressure increases to the inhalation pressure during a single breath, and also the profile at which the pressure change is presented to the patient. For

rise time, at a particular profile, a particular pressure is presented at a particular time. For instance, if the exhalation pressure is five cm H_2O and the inhalation pressure is ten cm H_2O, the five cm H_2O pressure differential is provided to the patient over the selected time period such that a particular pressure i.e., six point two, seven point two, and eight point five is presented to the patient at a specific time to the profile selected by the patient. In the preferred embodiment, the patient may select up to three separate profiles. Furthermore, to facilitate the decrease in the pressure from the higher inhalation pressure to the lower exhalation pressure as shown in FIG. 9, a fall time exponential profile is provided such that the inhalation pressure drops to the exhalation pressure within point four seconds. The exponential utilizes the inhalation pressure and the exhalation pressure's parameters for defining the exponential profile.

For patient comfort, sleep apnea treatment device A includes a baffling system for muffling the noise of blower 12. As shown in FIG. 1, the housing includes air inlet 80 wherein air is drawn from the ambient environment by blower 12. The air is presented to the blower through a catacomb baffle passageway 82 which acts as a muffler for the operation of the blower. Baffle passageway 82 includes a blower baffle chamber 84 which encircles the bottom of blower 12 where air is drawn from the air inlet into the blower. A first generally perpendicular passage 86 extends from blower baffle chamber 84 a general distance and then is directed to a second generally perpendicular passageway 88 and then is directed to a third generally perpendicular passageway 90 and ultimately to a fourth generally perpendicular passageway 92. The configuration of varying perpendicular angles of baffle passageway facilitates in distorting the noise created by blower 12 and also forces the noise upward. The baffle passageway 82 is enclosed by bottom housing 94 and at the top by blower motor mounting plate 96 which encloses the top of baffle passageway 82.

Blower mounting plate 96 includes blower port 98 enabling the lower portion of blower 12 to pass through the mounting plate into blower baffle chamber 84 for receiving air from the ambient environment. Sound filter 100 is disposed between blower mounting plate and baffle passageway 82 for absorbing sound waves which have been directed upward from baffle chamber walls. Furthermore, disposed between air inlet 80 and the entrance of baffle passageway 82 is vertical baffle 102 which directs sound waves vertically for being absorbed by filter 100 and also for being returned into housing assembly 10 by handle 104 which overlaps air inlet 80.

Accordingly, as shown in FIGs. 1, 2, 3, 4, 6 and 7, sleep apnea treatment device A mechanically includes a variable speed blower 12 having a variable speed motor 62 which is controlled by a motor driver 64 for varying the speed of the blower. The blower 12 receives air from the ambient environment and blows the air under pressure through a flow meter assembly 14 to a patient. The flow meter assembly 14 includes ports to enable the flow and pressure of the air to be measured by various sensors which relay the information to a microprocessor 18 which in turn controls the motor driver 64 for varying the speed of the blower 12. Sleep apnea treatment device A may be a bi-level machine wherein a higher inhalation pressures is provided and a lower exhalation pressure is provided. Thus, by continuously monitoring the flow and pressure through the flow meter assembly, the speed of variable speed blower may be continuously varied during operation of sleep apnea treatment device A to provide varying pressures for the treatment of sleep apnea.

FIGs. 6 and 7, illustrates schematically the operation of sleep apnea treatment device A. Microprocessor 18 controls motor driver 64 which controls a three phase brushless motor 62 which manipulates blower 12 to provide pressurized air to the patient. The air passes through flow meter assembly 14 which sends air to flow sensor 30 which

sends a signal to microprocessor 18. Microprocessor 18 utilizes flow calibration model 48 for calculating the air flow. Temperature sensor 54 located adjacent to pressure sensor 42 sends a temperature reading to microprocessor 18 for use in calculating a calibrated pressure depending on the pressure/temperature calibration factor 52 previously determined for that particular pressure transducer. Pressure sensor 32 sends a pressure signal to microprocessor 18 which converts the pressure utilizing that pressure conversion factor for that particular pressure transducer and also utilizing the auto offset calibration 56 previously calculated at startup of the system. By utilizing the flow value, the inhalation/exhalation detection sub-module is utilized for determining the amount of pressure to be provided to the patient by sleep apnea treatment device A as previously inputted into the system as the prescribed therapeutic inhalation and exhalation pressure levels 104. This pressure is compared to the actual pressure value determined by the microprocessor 18 and any fluctuation between the actual pressure measured and that treatment pressure which is intended to be provided, is utilized for controlling the motor driver 64 for varying the speed of the motor 62 of the blower 12 to provide the desired pressure. The operation of sleep apnea treatment device A is monitored by the patient compliance system 58 for monitoring the utilization of the system by the patient.

Thus it may be seen, that a more advantageous design for a sleep apnea treatment device providing continuous or bi-level positive pressure for the treatment of sleep apnea to a patient may be had according to the present invention. A low cost but reliable system may be had by establishing correction factors for pressure transducers and flow sensors to ensure the accurate operation of the sleep apnea treatment device wherein a variable speed blower may be manipulated on the readings from a single flow meter device for providing positive air pressure treatment to a patient.

What is claimed is:

1. A device for the treatment of sleep apnea; said device comprising:

a variable-speed blower for providing an airflow under pressure to a patient for treating sleep apnea;

a motor controller interconnected with said variable speed blower for manipulating the speed of said blower to provide air at a predetermined pressure;

a flow meter assembly inline between said variable speed blower and a patient for receiving said airflow, said flow meter assembly including a flow port communicating a portion of said airflow to a flow sensor for measuring the flow of said airflow and a pressure port in communication with a pressure sensor for measuring the pressure of said airflow;

an input device for inputting said predetermined pressure of said airflow; and

a microprocessor for receiving the inputted desired pressure and said flow measured by said flow sensor and said pressure measured by said pressure sensor, said microprocessor controlling the operation of said motor controller for manipulating the airflow provided by said variable speed blower depending on the values of said inputted predetermined pressure, said measured flow and said measured pressure.

2. The device of claim 1 wherein said predetermined pressure is a first pressure to be presented to a patient for inhalation, and a second pressure to be presented to a patient for exhalation.

3. The device of claim 2 wherein a transition between said first pressure and said second pressure is controlled by said microprocessor wherein said transition occurs within a single breath of a patient and specific transitional pressures are provided by said blower at specific time intervals within said transition period.

4. The device of claim 2 wherein a transition between said second pressure and said first pressure is controlled by said microprocessor wherein said transition occurs within a single breath of a patient and specific transitional pressures are provided by said blower at specific time intervals within said transition period.

5. The device of claim 1 further comprising a flow calibration factor for said flow sensor wherein a voltage measured by said flow sensor is adjusted by said flow calibration factor for determining the flow of said air through said flow meter.

6. The device of claim 5 wherein said flow calibration factor is a fourth order polynomial.

7. The device of claim 1 further comprising a temperature sensor for sensing the approximate temperature of said pressure sensor.

8. The device of claim 7 further comprising a pressure/temperature calibration factor wherein the pressure measured by said pressure sensor is adjusted by said pressure/temperature calibration factor depending on the value of the temperature sensed by said temperature sensor for determining the pressure of said air.

9. The device of claim 1 further comprising a housing having an air inlet for communicating air from the ambient environment to said blower.

10. The device of claim 9 further comprising a baffle passageway defining a torturous airway path from said air inlet to an inlet of said blower.

11. The device of claim 10 wherein said baffle passageway includes a blower baffle chamber including at least three sidewalls extending from a base of said housing encircling said blower inlet.

12. The device of claim 11 further comprising a blower mounting plate for mounting said blower within said housing, said blower mounting plate including a blower inlet port enabling an inlet of said blower to extend into said blower baffle chamber, said blower mounting plate covering said blower baffle chamber.

13. The device of claim 11 further comprising a sound filter disposed between said blower mounting plate and said baffle passageway for absorbing sound.

14. The device of claim 10 further comprising a vertical baffle disposed between said air inlet and said baffle passageway for directing soundwaves upward toward said housing.

15. The device of claim 1 wherein said flow meter includes a first flow port for directing a portion of air flow to said flow sensor and a second flow port for receiving said portion of air flow from said flow sensor and for returning said portion of air flow to said flow meter for delivery to a patient.

16. The device of claim 15 wherein said flow meter includes a screen disposed between said first and second flow ports for creating a pressure drop inducing a portion of air flow to separate from the air flow stream from said blower to said enter said first flow port for delivery to said flow sensor.

17. A method of manufacturing a sleep apnea treatment device, said method comprising:

a.) providing a first flow sensor for incorporation into said sleep apnea treatment device;

b.) providing a control flow sensor;

c.) passing a predetermined flow level to said control flow sensor for providing a control flow parameter;

d.) passing said predetermined flow level to said first flow sensor for providing a measured voltage parameter;

e.) repeating steps c and d at least five times at different predetermined flow levels creating at least five pairs of flow data points which consist of the control flow parameter and the measured corresponding voltage parameter of said first flow sensor at a predetermined control flow level;

f.) creating a flow model utilizing said five pairs of flow data points to establish a correlation between said control flow parameters and said measured voltage parameters; and

g.) integrating said flow model within said sleep apnea treatment device.

18. The method of claim 17 wherein said regression model is a fourth order polynomial.

19. The method of claim 17 wherein said first flow sensor is a mass airflow sensor.

20. A method of manufacturing a sleep apnea treatment device, said method comprising:

a.) providing a first pressure sensor for incorporation into said sleep apnea treatment device;

b.) providing a known pressure to said first pressure sensor over a series of different predetermined temperatures to establish control pressure parameters;

c.) determining the pressure measured by said first pressure sensor at said different predetermined temperatures;

d.) measuring the difference between said known pressure and said measured pressure at a predetermined temperature;

e.) repeating steps b, c and d at least two times at different predetermined temperatures creating at least two pairs of pressure data points which consist of the control pressure parameter and measured pressure parameter at said predetermined temperature;

f.) creating a pressure/temperature model utilizing said pairs of pressure data points to establish a correlation between said control pressure parameters and said measured pressure parameters; and

g.) integrating said pressure/temperature model within said sleep apnea treatment device.

21. The method of claim 20 wherein said steps b, c and d are repeated at least three times at different predetermined temperatures creating at least three pairs of pressure data points.

22. A method of monitoring patient compliance with a sleep apnea treatment device; said method comprising:

providing a clock;

monitoring a flow of air to determine if a breath has been taken by a patient;

determining if at least a predetermined number of breaths have been taken by a patient to determine if a patient is utilizing the sleep apnea treatment device;

noting that the sleep apnea treatment device is in operation if at least said predetermined number of breaths have been determined;

noting the time that the sleep apnea device is in operation;

noting that the sleep apnea treatment device is not in operation if at least said predetermined number of breaths have not been determined; and

noting the time that the sleep apnea device is not in operation.

23. The method of claim 22 wherein said predetermined number of breaths to be monitored for determining if a patient is utilizing the sleep apnea treatment device is at least four.

24. The method of claim 22 further comprising the step of determining if the sleep apnea treatment device has been powered up and also including the step of noting the time when said sleep apnea treatment device is powered up.

25. A flow meter assembly for monitoring the flow and pressure of an airflow; said flow meter assembly comprising:

a flow meter inlet for receiving an airflow;

a first flow meter port for directing at least a portion of the airflow to a flow sensor;

a second flow meter port for receiving at least a portion of the airflow from a flow sensor; and

a pressure port for communicating the pressure of said airflow to a pressure sensor.

26. The flow meter assembly of claim 25 further comprising a pressure drop screen disposed between said first and second flow meter ports for creating a pressure drop inducing at least a portion of the airflow to flow to a pressure sensor.

27. The flow meter assembly of claim 26 wherein said pressure port is disposed downstream from said second flow meter port.

28. The flow meter assembly of claim 27 further comprising a second screen disposed between said second flow meter port and said pressure port.

29. The flow meter assembly of claim 25 further comprising a blower connection for fluidly communicating said flow meter assembly with a blower.

30. The flow meter assembly of claim 29 further comprising a blower connection screen disposed between said blower connection and said first flow meter port.

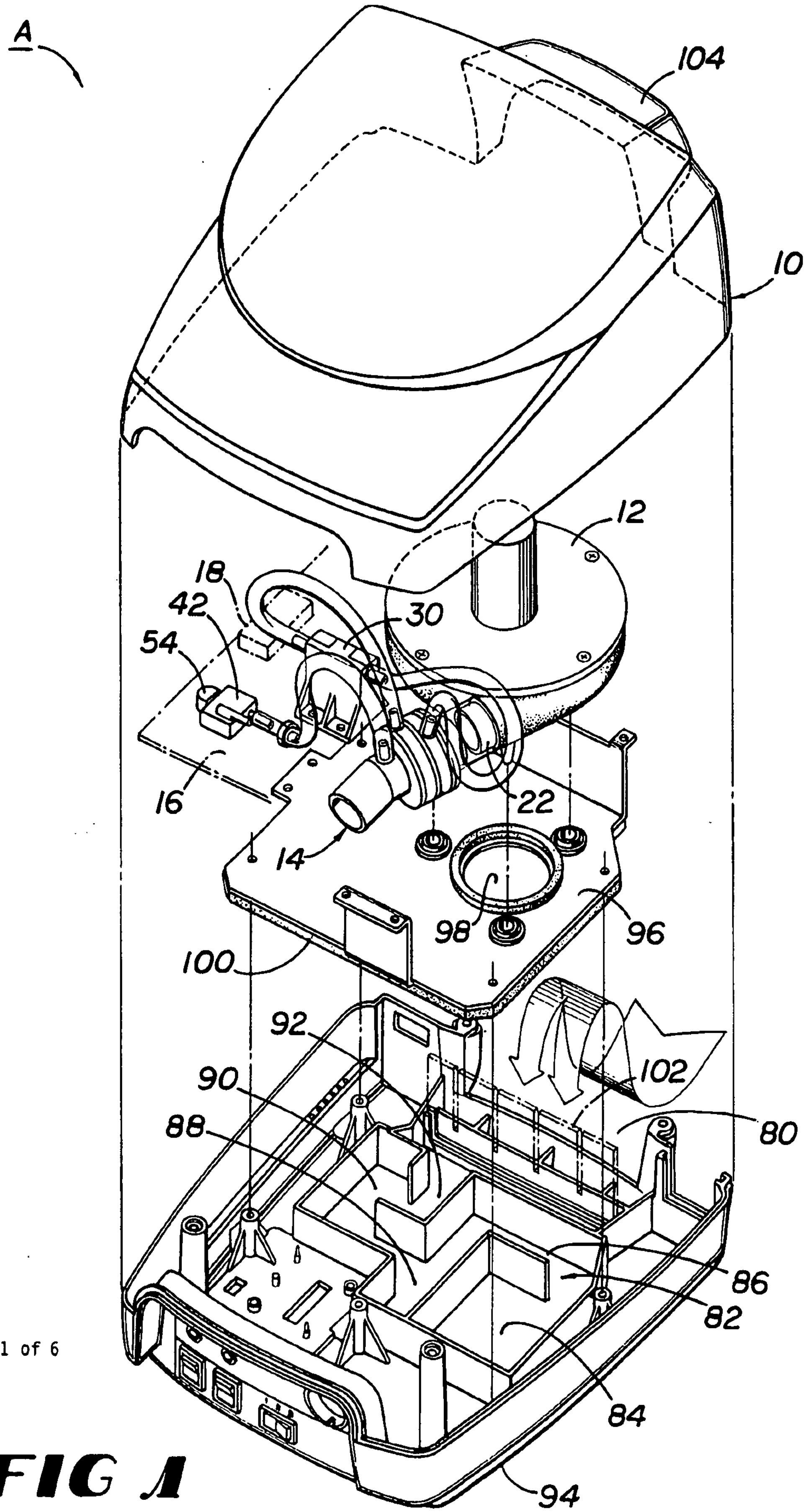

FIG 1

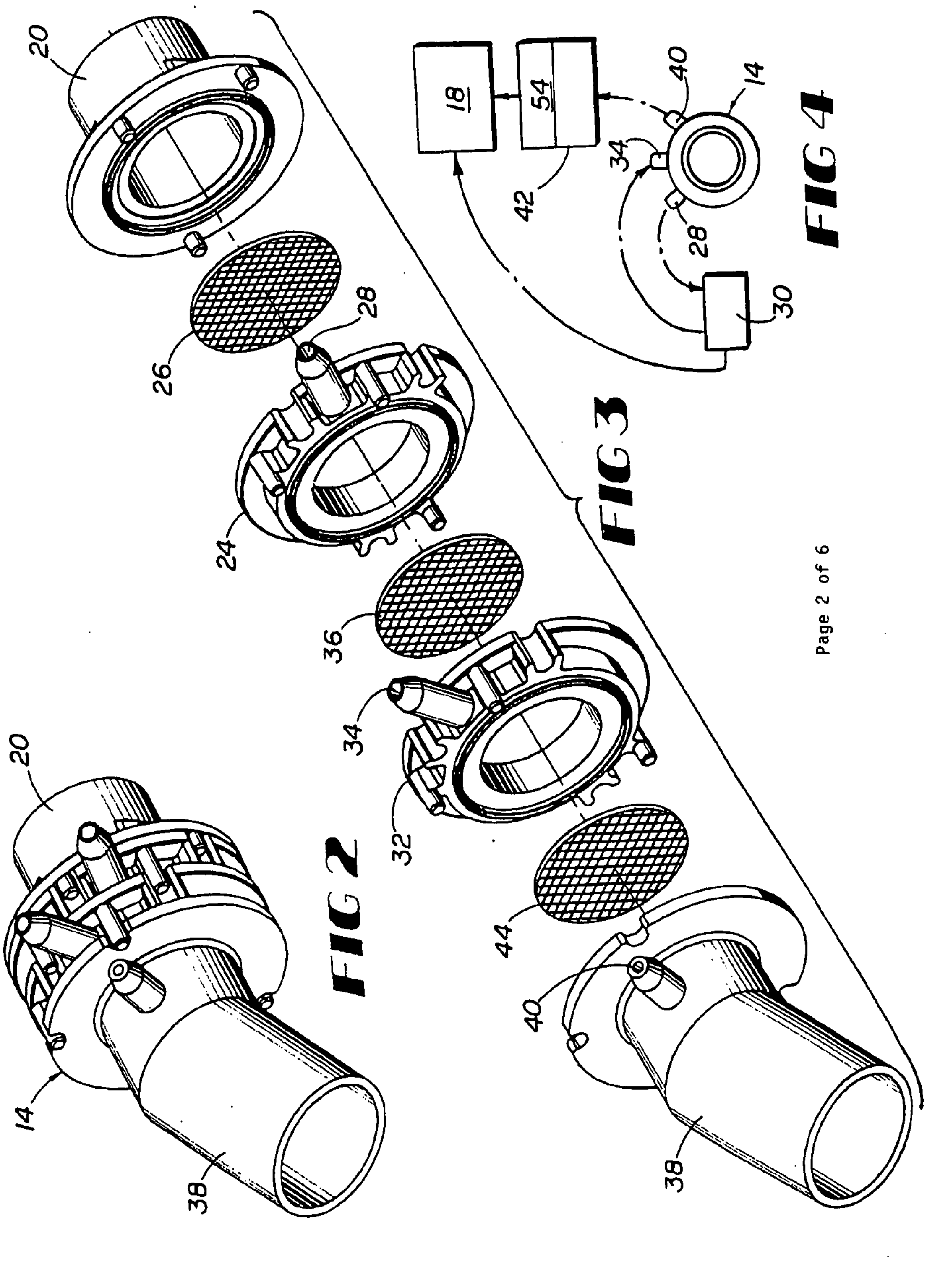

FIG 2

FIG 3

FIG 4

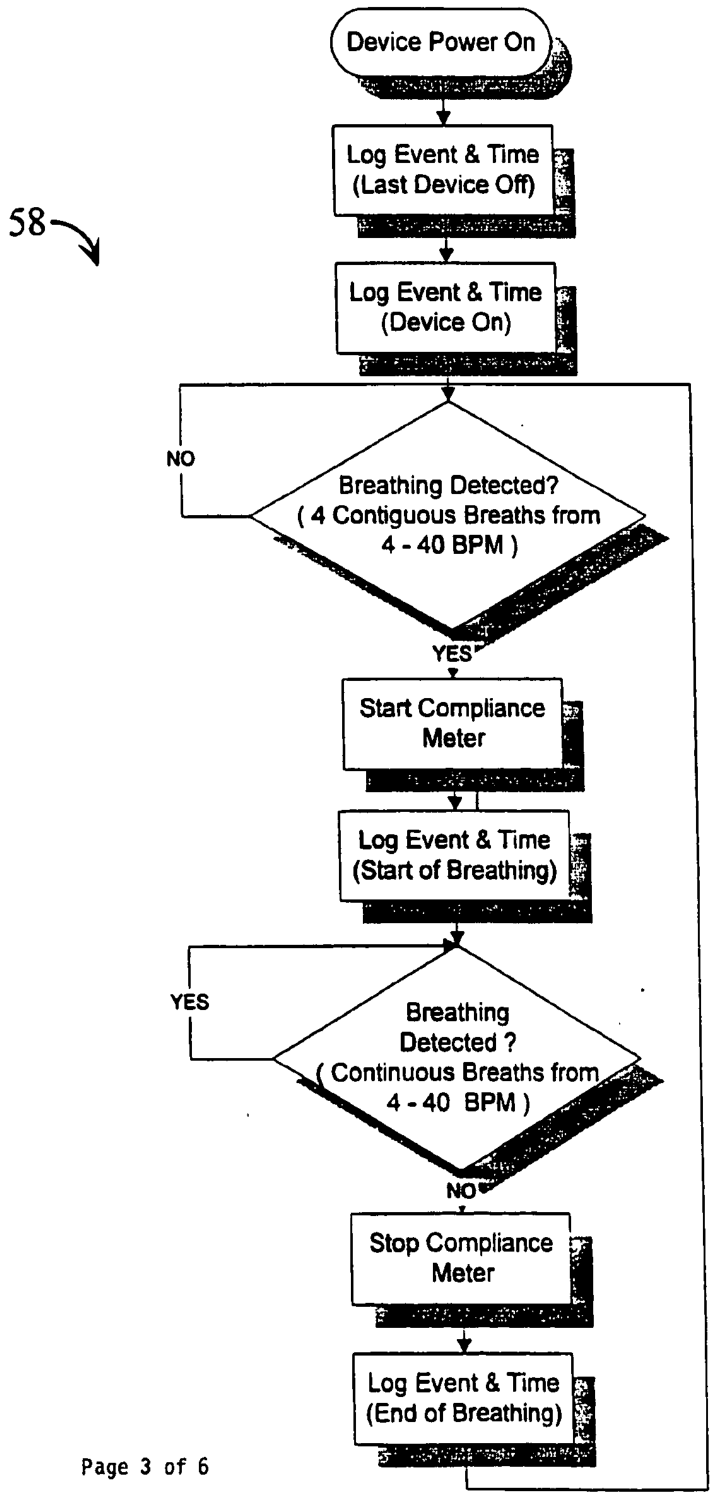
58
Device Power On
Log Event & Time
(Last Device Off)
Log Event & Time
(Device On)
NO
Breathing Detected?
(4 Contiguous Breaths from
4 - 40 BPM)
YES
Start Compliance
Meter
Log Event & Time
(Start of Breathing)
YES
Breathing
Detected ?
(Continuous Breaths from
4 - 40 BPM)
NO
Stop Compliance
Meter
Log Event & Time
(End of Breathing)

FIG. 5

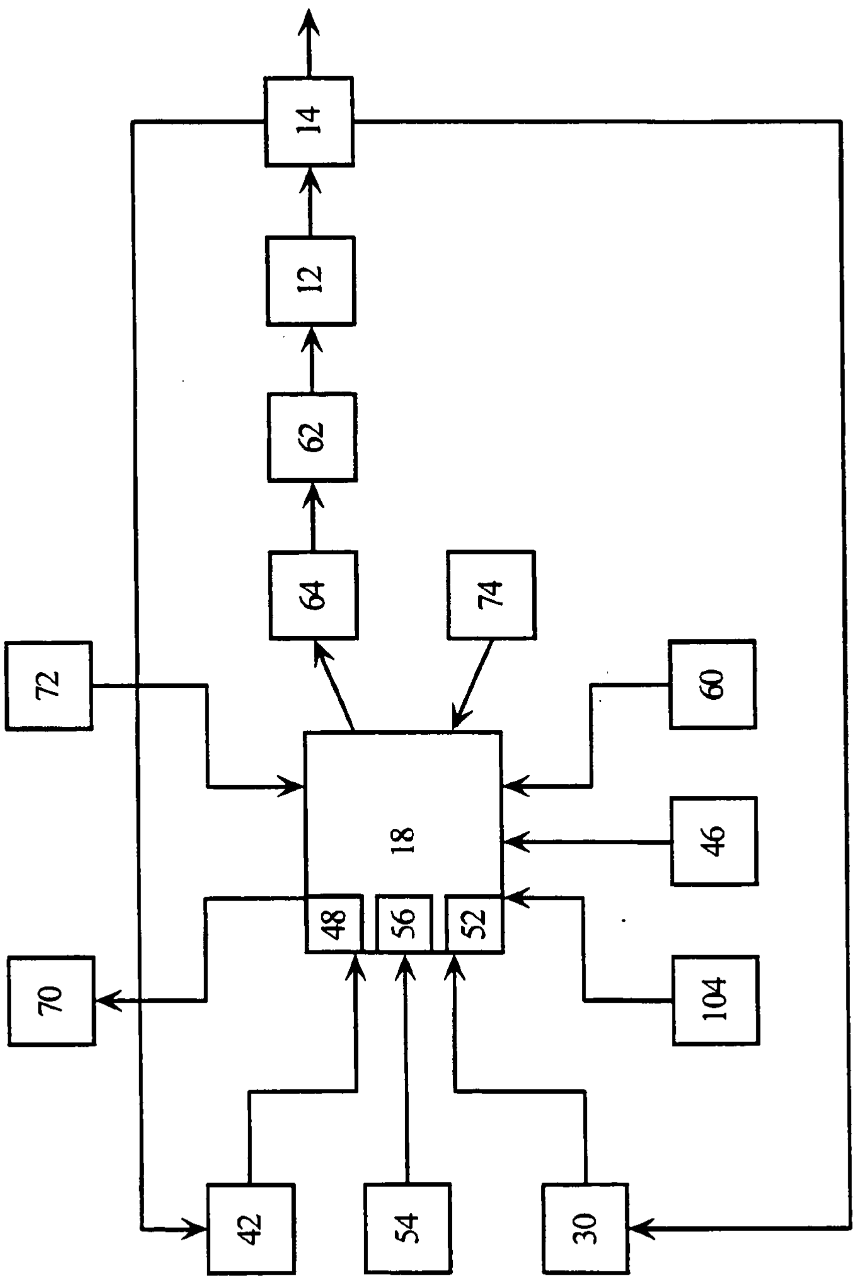

FIG. 6

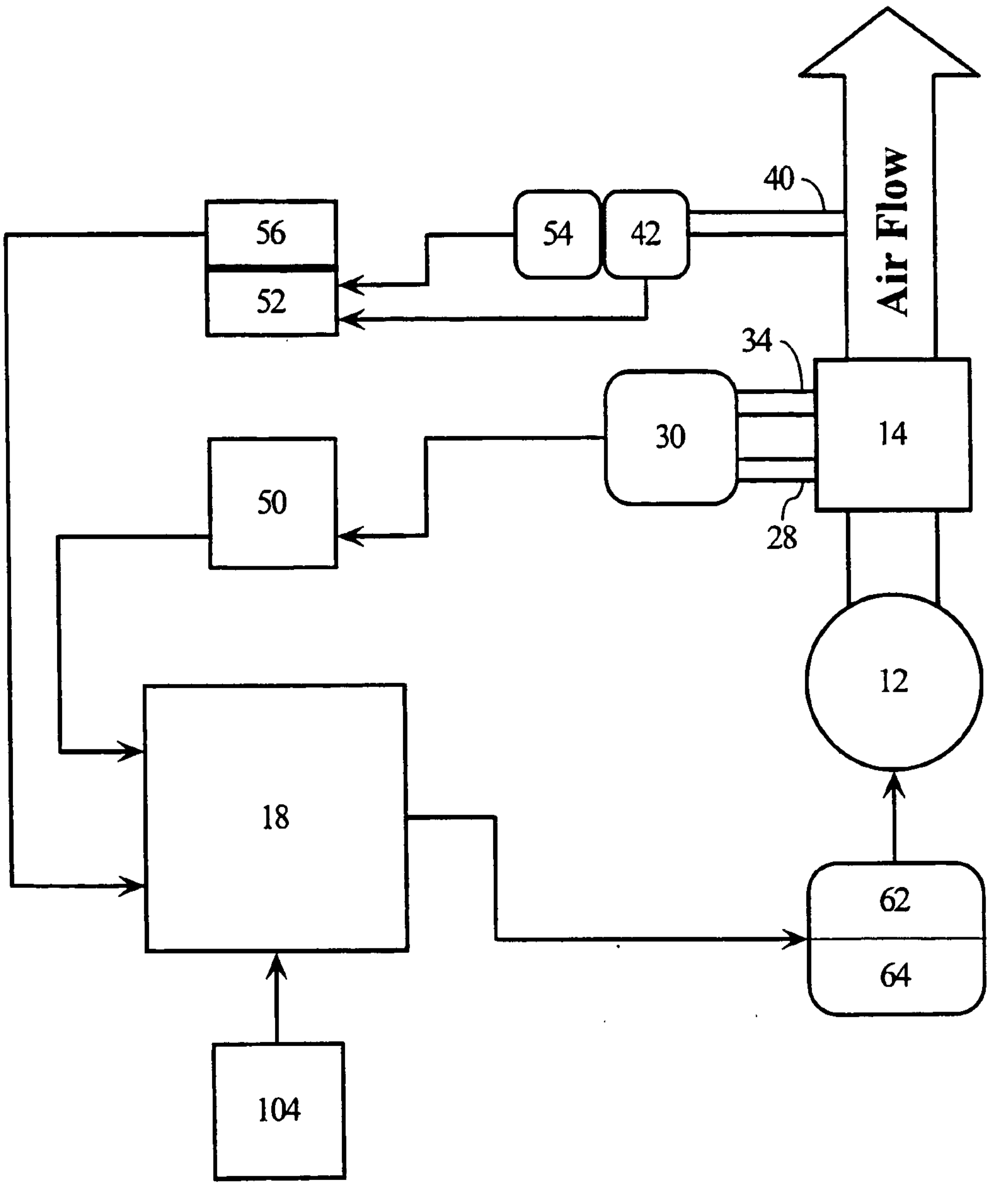

FIG. 7

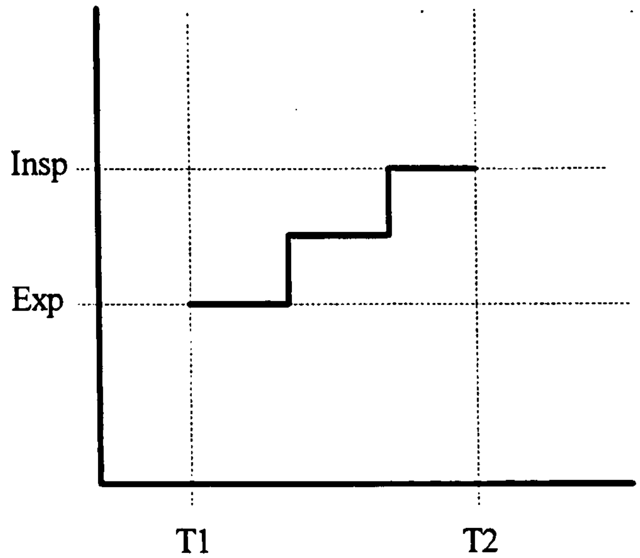

FIG. 8

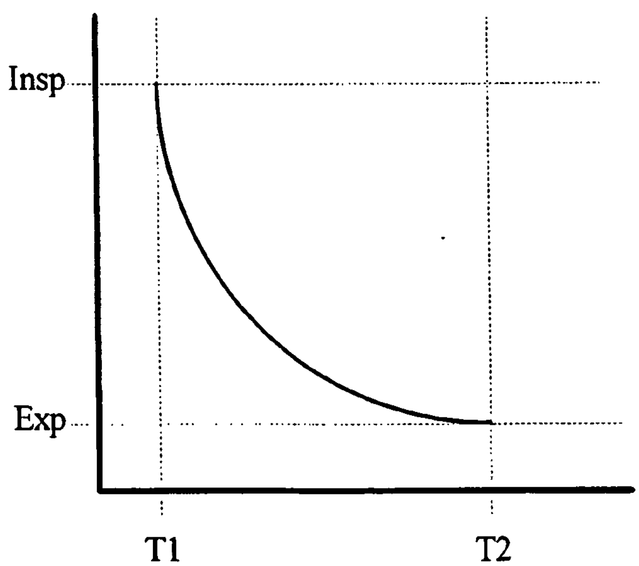

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01987

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 5/08; A61M 16/00; A62B 7/00; F16K 31/02
US CL :128/204.18, 204.21; 204.23,
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/204.18, 204.21; 204.23, 205.27, 206.18, 207.18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,199,424 A (SULLIVAN et al) 06 April 1993, entie disclosure.	1-30
Y	US 5,458,137 A (AXE et al) 17 October 1995, entire document.	1-30
Y	US 5,535,738 A (ESTES et al) 16 July 1996, entire disclosure.	1-30
Y	US 5,537,997 A (MECHLENBURG et al) 23 July 1996, entire document.	1-30
Y	US 5,549,106 A (GRUENKE et al) 27 August 1996, entire document.	1-30
Y,P	US 5,647,351 A (WEISMANN et al) 15 July 1997, entire document.	1-30

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

11 JUNE 1998

Date of mailing of the international search report

23 JUN 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer
FOR
KIMBERLY ASHER

Telephone No. (703) 308-0332

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

Group I, claims 1-16 drawn to an apnea treatment device.

Group II, claims 17-21, drawn to a method of manufacturing an apnea device.

Group III, claims 22-24, drawn to a method of monitoring patient compliance.

Group IV, claims 25-30, drawn to a flow meter.

The inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

Group I does not require the flow meter of Group IV, the compliance monitor of Group III, nor the manufacturing method of Group II.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01987

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y,P	US 5,694,923 A (HETE et al) 09 December 1997, entire document.	1-30
Y	US 5,517,983 A (DEIGHAN et al) 21 May 1996, entire document.	22-24